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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/225,080	01/04/99	AU-YOUNG	J PF-0066-2-DI

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HM12/0706

EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 07/06/00

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/225,080

Applicant(s)

Au-Young

Examiner

Karen Canella

Group Art Unit
1642



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 months month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 13, 17, and 19-39 is/are pending in the application

Of the above, claim(s) 13, 17, and 19-38 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 39 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1642

DETAILED ACTION

1. Claims 1, 17 and 19-39 are pending.

Claims 34-39 have been added and claim 18 has been canceled by preliminary amendment filed 4/17/00.

Claims 13, 17 and 19-38, drawn to non-elected inventions, have been withdrawn from consideration.

Claim 39 is examined on the merits.

2. Applicant's election with traverse of Group III, claim 39, drawn to a polypeptide, in Paper No. 6, filed 4/17/00 is acknowledged. The traversal is on the grounds that the searches for Groups I to XIII would not substantially overlap and therefore would not pose an undue search burden on the examiner. This is not found persuasive. The inventions of Groups I, III, IV, X and XI are drawn to different products unrelated in structure or function. The methods of Groups II, V-IX, XII and XIII differ in method objectives, method steps and parameters and the reagents used.

In addition, Applicant argues that the method of Group II should have been included with the claims of the now issued parent application, and thus should be included with the examination of Group III of the instant application. This is not found persuasive. Group II of the instant application is drawn to a method of detecting an expression product by means of nucleic acid hybridization, and is thus a method of using the polynucleotide product, unrelated to the polypeptide product. In addition, the polypeptides and the hybridization method of the instant application are classified differently, necessitating different searches in the U.S. Patent shoes.

Classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search for the products of inventions of Groups I, III, IV, X and XI and methods of Groups II, V-IX, XII and XIII is not co-extensive and is much more

Art Unit: 1642

important in evaluating the burden of search in each group. Clearly different searches and issues are involved in the examination of each invention.

However, the policies set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86 will be followed. Method claims limited to the scope of the allowable product claims will be rejoined and examined at the time the product claims are indicated as being allowable.

For these reasons the restriction requirement is deemed to be proper and is adhered to. The requirement is therefore made FINAL.

Information Disclosure Statement

Lined-through references on applicant's PTO-1449 (filed 1/4/99) have not been considered by the examiner as copies of the cited references were not found in the parent file (08/675,508). Applicant is invited to provide replacement copies.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 39 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

-Claim 39 recites "d) a naturally-occurring amino acid sequences having at least 90% sequence identity to the sequence of SEQ ID NO:2". It is not clear how the origin of the amino acid (naturally occurring vs synthetic) effects the requirement of 90% homology to SEQ ID NO:2. For purposes of examination, all amino acid sequences having 90% homology to SEQ ID NO:2 will be included in this claim.

Art Unit: 1642

-Claim 39 recites "(e) a biologically active fragmentthe amino acid sequence of SEQ ID NO:2". What biological activities of the fragment are encompassed by the claim is unclear. For purposes of examination, the part e) of the claim will read on all fragments of the amino acid sequence of SEQ ID NO:2.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 39 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the amino acid sequence of SEQ ID NO:2, does not reasonably provide enablement for naturally occurring amino acid sequences having at least 90% sequence identity to SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There is no instruction in the specification for using all sequences having 90% homology to SEQ ID NO:2. Without further guidance or working examples from the specification instructive for relating sequence changes to functional activity of the desired altered polypeptide, one of skill in the art would not know how to use any polypeptide having 90% homology to SEQ ID NO:2.

7. Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are broadly drawn to naturally occurring amino acid sequences comprising 90% sequence identity to SEQ ID NO:2 and naturally occurring amino acid sequences

Art Unit: 1642

comprising fragments of the amino acid sequence of SEQ ID NO:1. The specification discusses only SEQ ID NO:2. The number of theoretical sequences encompassed by parts d, e, and f of this claim is legion. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing. Therefore, one of skill in the art would not be convinced that applicant had possession of more than SEQ ID NO:2 at the time of filing.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by any of Wilkie et al (Genomics, 1993) or Wray et al (Gene 1993) or Burton (Nature, 1993) or Gama et al (Mol. Microbiol., 1992) or Birkeland (Can J. Microbiol., 1994) or Arendt et al (Appl. Environ. Microbiol., 1994). Claim 39 is drawn to immunogenic polypeptide fragments of SEQ ID NO:2. Any of the above have disclosed a purified polypeptide comprising a fragment of the amino acid sequence of SEQ ID NO:2 which can generate an immune response in the proper host.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are

Art Unit: 1642


unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

June 30, 2000



NANCY A. JOHNSON, PH.D
PRIMARY EXAMINER